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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,936	02/14/2001	Vivian E. Mack Strong	19603/4071(CRF-D-2598A)	1665

7590 09/11/2003

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EXAMINER

ROSE, SHEP K

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/11/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782936

Applicant(s)

Examiner

SIDOP ROSE

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 3/11/03

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1 15 24627 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1 15 24627 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1617

Claims 10, 15, 24 to 27 are generic to a plurality of disclosed patentably distinct species comprising one ultimate species of each of :

- (a) A cox-2-inhibitor species of claim 15; and one of (B) to (G) (below)
- (b) a patient species treated for one of : trauma, burn injury, penetrating injury, fracture or surgery, or else
- (c) a patient prophylaxes method at risk for systemic inflammatory response syndrome, or else:
- (d) a patient treatment method of patient having systemic inflammatory response syndrome;
- (e) or a species of complication thereof of (C) ;
- (f) or a species of complication thereof of (D) or else:
- (g) (if further elected) treating sepsis (as in the title of this case)

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, of (A) and one of (B) to (G), even though this requirement is traversed. If this application is filed under Rule 371, the legal authority is PCT Rule 13.2, Annex B, part 1 (f) "Markush Practice"; PCT Rule 13 and 35 U.S.C. § 372, rather than 35 U.S.C. § 121.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention.

Election of species is required per MPEP § 803, 809.02 (d) (Markush group claim practice, separate and burdensome fields of search required).

Patentably distinct Markush species are independent inventions, In re Webber, 198 USPQ 328, In re Haas, 198 USPQ 334. Divisional applications may be filed under 35 U.S.C. § 121, as a result of an office requirement for an election of a patentably distinct species as made herein. In re Joyce, 115 USPQ 412, In re Herrick, 115 USPQ 412. This satisfies the "patentably distinct" criterion since the Examiner is not of the opinion that the various species are obviously unpatentable over one another, and each species (as noted above) is capable of independent manufacture, use, and sale, with the other components of the claimed formulations.

Applicant is further required to identify the claims that correspond to the elections as well as those that do not even if the requirements are traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday, and Thursday 7:30am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Rose/tgd
September 9, 2003



Shep Rose
Senior Primary Examiner
Art Unit 1614

**SHEP K. ROSE
PRIMARY EXAMINER**